

medical devices



Medical Device Reporting for Distributors



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Services
Food and Drug Administration

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Medical Device Reporting for Distributors

Prepared by
Office of Surveillance and Biometrics
Division of Surveillance Systems



April 1996

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Services
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

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FOREWORD

The Center for Devices and Radiological Health (CDRH), part of the Food and Drug Administration (FDA), develops and implements national programs and regulations to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness, and proper labeling of medical and radiation-emitting devices.

The Center publishes the results of its work in scientific journals and in its own technical reports. Through these reports, CDRH also provides assistance to industry and to the medical and health professional community in complying with the laws and regulations mandated by Congress. The reports are sold by the Government Printing Office (GPO) and/or by the National Technical Information Service (NTIS). Many reports are also available on the Internet/World Wide Web.

We welcome your comments and requests for further information.

A handwritten signature in dark ink, reading "D. Bruce Burlington". The signature is written in a cursive, flowing style.

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

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PREFACE

The final regulation for reporting adverse events involving medical devices, applicable to both device user facilities and manufacturers, was published in the December 11, 1995, *Federal Register* and becomes effective on July 31, 1996. This regulation implements the reporting requirements contained in the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992.


Much of the information in this document is general in nature and may not apply to a specific situation. Questions should be sent by facsimile (FAX) to (301) 827-0039 or mailed to:

Food and Drug Administration
Center for Devices and Radiological Health
Division of Surveillance Systems (HFZ-530)
Medical Device Reporting (MDR) Inquiries
1350 Piccard Drive
Rockville, MD 20850

Please include your name, return address, telephone number, and (if applicable) FAX number with your questions.

This guidance for distributors is one of three documents written for a particular audience: user facilities, manufacturers, and distributors. All are available through the Internet/World Wide Web at: <http://www.fda.gov> and after June 1996, from the National Technical Information Service, Springfield, Virginia 22161, telephone no. (703) 487-4650. Other MDR documents are:

- Medical Device User Facility and Manufacturer Reporting, Certification and Registration . . . Final Rules. December 11, 1995, *Federal Register*, pp. 63578-63607.
- FDA Form 3500A (Mandatory MedWatch)
- Instructions for Completing Form 3500A with Coding Manual for Form 3500A
- Abbreviated Instructions: Mandatory MedWatch Form 3500A
- MDR Semiannual Report Form FDA 3419
- MDR Baseline Report Form FDA 3417
- MDR Annual Certification Form FDA 3381
- Medical Device Reporting for User Facilities
- Medical Device Reporting for Manufacturers (draft)
- Medical Device Reporting: An Overview
- *User Facility Reporting Bulletin* - all issues


Larry G. Kessler, Sc.D.
Director
Office of Surveillance and Biometrics

CONTENTS

Foreword	iii
Preface	v
Introduction	1
Scope	1
Purpose	1
Definitions	1
Distributor	1
Distributor report number	1
Incident files	1
“Information that reasonably suggests”	1
Malfunction	1
Manufacturer	2
Probability, probable, or probably	2
Serious illness	2
Serious injury	2
Work day	2
Public availability of reports	2
Reports by Distributors	5
Overview of distributor reporting requirements	5
For a distributor of domestic devices	5
Importer	5
Other types of report/submissions	6
Distributor annual certification	6
Additional information requests	6
Miscellaneous	6
Supplemental information	6
Disclaimer	7
Record keeping requirements	7
Written procedures	7
Individual adverse events reports	8
Exemptions and alternative reporting	8
Procedure for Reporting Adverse Events	9
Steps for reporting adverse events: “questions to ask”	9
Am I a distributor as defined in the MDR regulations?	9
What kind of distributor am I?	9
From whom or where was the information about the event received?	9
As a domestic distributor, when and to whom do I file reports?	9

As an importer, when and to whom do I submit reports?	10
Submit a written report or additional information within 10 working days	10
Questions and Answers	11
Appendix A. Distributor Annual Certification Schedule	13
Appendix B. Form FDA 3381 (Medical Device Report - Annual Certification)	14
Appendix C. FDA Form 3500A (mandatory MedWatch form)	16
Figure 1. Distributor Report Flow Chart	18

This guidance does not create or confer any rights, privileges or benefits for or on any person, nor does it operate to bind FDA or any other person. The agency will consider individual circumstances on a case-by-case basis. Where this document reiterates a requirement imposed by statute or regulation, the force and effect as law of the requirement is not changed in any way by virtue of its inclusion in this document.

1. INTRODUCTION

1.1 Scope

This guidance is directed to distributors of domestic and imported medical devices. FDA is requiring medical device distributors to report deaths and serious injuries that are attributed to medical devices. Distributors are also required to report certain device malfunctions and to annually submit a report to FDA certifying the number of medical device reports filed during the preceding year or that no reports were filed. The MDR regulation provides a mechanism for FDA to identify and monitor significant adverse events involving medical devices, so that problems may be detected and corrected in a timely manner. These reports enable FDA to protect the public health by helping to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for their intended use.

1.2 Purpose

The purpose of this document is to provide guidance and help device distributors understand the basic requirements for reporting adverse events involving medical devices. The reporting requirements are based on the final rule which was published in the September 1, 1993 *Federal Register*.

1.3 Definitions [§804.3]

■ Distributor

A distributor is person, including any person who imports a device into the United States, who furthers the marketing

of a device from the original place of manufacture to the person who makes final delivery to the ultimate user but does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

■ Distributor report number

A distributor report number uniquely identifies each report submitted by a distributor. Distributors who receive or submit reports must use their seven digit FDA registration number, calendar year that the report is received, and a sequence number.

■ Incident files

Incident files are those files containing documents or other information that are related to adverse events which may have been caused by a device.

■ "Information that reasonably suggests that there is a probability that a device has caused or contributed to a death or serious injury or serious illness".

This statement means information, including professional, scientific, or medical facts, observations, or opinions, which would cause a reasonable person to believe that a device caused or contributed to a death, serious injury, or serious illness.

■ Malfunction

A malfunction is the failure of a device to meet its performance specifications or otherwise to perform as intended.

■ **Manufacturer**

A manufacturer is any person who manufactures, prepares, propagates, compounds, assembles, or processes a device chemically, physically, biologically, or by other procedures. The term includes any person who:

- Repackages or otherwise changes the container, wrapper, or labeling of a device to further the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user or consumer;
- Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or
- Manufactures components or accessories which are devices that are ready to be used and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

■ **Probability, probable, or probably**

These terms mean that a person would have reason to believe, based upon an analysis of the event and device, that the device has caused or contributed to an adverse event. This term does not signify statistical probability.

■ **Serious illness**

Serious illness means an event that:

- is life threatening;

- results in permanent impairment of a body function or permanent damage to the body structure; or
- necessitates immediate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure.

■ **Serious injury**

Serious injury means an event that:

- is life threatening;
- results in permanent impairment of a body function or permanent damage to a body structure; or
- necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure.

■ **Work day**

Work day means Monday through Friday excluding Federal holidays. Federal holidays include New Year's Day, Martin Luther King Jr.'s Birthday, Presidents' Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day.

1.4 Public availability of reports **[\$804.9]**

All reports submitted to FDA are available for public disclosure. However, before public disclosure, FDA will delete information that involves trade secrets or confidential commercial or financial information and any personnel, medical, or

similar information which would constitute an invasion of personal privacy. A patient, however, may request and receive from FDA, a report that contains all information in the report concerning that patient. The requests for reports should be in writing

and sent to:

Food and Drug Administration
Attn: Freedom of Information Staff
5600 Fishers Lane, HFI-35
Rockville, Maryland 20857

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2. REPORTS BY DISTRIBUTORS

2.1 Overview of distributor reporting requirements [§804.25]

Figure 1 (on page 19) contains a flow chart of the distributor reporting requirements which should be reviewed in conjunction with this section.

The following is a brief overview of distributor reporting requirements which differ slightly for distributors that are not importers and distributors that are importers of medical devices:

■ For a distributor of domestic devices

A distributor, other than an importer, is required to report both to FDA and the device manufacturer whenever becoming aware of information that reasonably suggests there is a probability that a device it marketed has caused or contributed to a death, serious illness, or serious injury. These distributors are also required to report to the manufacturer when they become aware that one of the devices they marketed has malfunctioned; and, such information reasonably suggests that there is a probability that the device or any other device marketed by the distributor would cause a death, serious illness, or serious injury if the malfunction were to recur.

■ Importer

Importers of medical devices are also required to report to FDA and the manufacturer whenever they receive or become

aware of information that reasonably suggests that one of their marketed devices may have caused or contributed to a death or serious injury. They are also required to report to the manufacturer when they become aware that one of the devices they marketed has malfunctioned and that such device or similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Like hospitals and other medical facilities, distributors are required to report using FDA FORM 3500A (mandatory MedWatch form) within 10 work days after becoming aware of the information. FDA believes the distributor becomes aware of the information when any employee of the distributor becomes aware of information indicating a reportable event has occurred.

NOTE: Although the language of the reporting standards for domestic distributors and importers is slightly different (e.g., "has caused or contributed"; "would cause or contribute"; "may have caused or contributed"; and "would be likely to cause or contribute"), FDA believes the standards for distributors, both importers and non-importers as they relate to the reporting requirements, is essentially the same. The intention of each of these requirements is to enable FDA to protect the public health by helping to ensure that devices are safe and effective for their use.

2.2 Other types of reports/submissions

■ Distributor annual certification [§804.30]

Distributors must annually submit certification reports to FDA. In the reports, distributors must certify the number of medical reports submitted to FDA or the appropriate manufacturer during the previous twelve month period; that all reports required to be submitted were, in fact, submitted; or that no reports were received during this period. The reports must also include the name, address, and tele-phone number of the distributor and the firm's FDA registration number.

The seven digit registration number is obtained from FDA when the firm registers within 30 days after beginning business. However, if a distributor has no assigned identification number, it should use all zeros in the appropriate space on the initial report. Until the distributor receives an FDA-assigned identification number, the distributor should continue to use all zeros on subsequent reports.

The distributor's annual certification report is to be submitted by the date designated for annual registration for the firm. This date covers the period ending one (1) month before the month of the scheduled date of mailing. Annual certification reports (see Appendix A) are sent to:

Food and Drug Administration
Center for Devices and
Radiological Health (HFZ-531),
Distributor Report
P.O. Box 3002
Rockville, Maryland 20850

In addition, the name, address, telephone number, and signature of a responsible person designated by the firm to make such certification must be included in the report.

Although an annual certification form for submitting annual certifications reports by distributors has been developed, it is not required by Title 21 Code of Federal Regulations (CFR) Part 804. We anticipate that the use of the form will become mandatory in the near future and are, therefore, encouraging distributors to voluntarily use the form for such purpose since it outlines all necessary information. A copy is included in Appendix B.

■ Additional information requests [§804.31]

There may be times when FDA determines that information, in addition to that included in a medical device report, is needed for the protection of the public health. In such instances, FDA will request additional information from the distributor and state in the request the reason and purpose for requesting the information. FDA will also give the distributor a due date for submission of the information.

2.3 Miscellaneous

■ Supplemental information [§804.32]

The distributor does not have to file reports if it determines that the information received is erroneous because no death, serious injury, serious illness, or malfunction occurred or that the device that is the subject of the information was distributed by another distributor.

■ Disclaimer [§804.32(c)]

The report or information provided by the distributor does not reflect a conclusion that the report or information is an admission that the device, establishment filing the report, or employees caused or contributed to a death, serious injury, serious illness or malfunction. The distributor may deny that the report or information submitted is such an admission.

2.4 Record keeping requirements [§804.35]

Device distributors are subject to record keeping requirements related to medical device adverse event reporting. Specifically, they are required to establish device complaint files and maintain records of any information, written or oral, concerning all reportable events and events reviewed for determining whether or not to report. Device incident records must be prominently identified as such and filed by device. Also, the files shall contain a copy of any MDR report along with any additional information submitted to FDA and documentation of the submission of copies of MDR reports to manufacturer. Distributors must keep records related to an event for two (2) years from the date that the report or additional information is submitted to FDA or for a period of time equivalent to the design or expected life of the device, whichever is greater.

Authorized FDA employees are permitted to have access to all required records at all reasonable times to copy and verify them.

2.5 Written procedures [§803.34]

Distributors must maintain and implement written procedures for reporting adverse medical device events. Such procedures must include procedures for:

- timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;
- a standardized review process/procedure for determining when an event is reportable;
- timely submission of complete MDR reports to FDA and/or manufacturer;
- training and education programs informing employees about the reporting requirements and how to identify and report MDR events; and
- documentation and record keeping requirements.

Procedures for documentation and record keeping must include:

- information that may be the subject of an MDR report;
- all MDR reports and information sent to FDA and manufacturers;
- back-up information for certification reports; and
- systems that ensure access to information that supports timely follow

up and inspection by FDA.

2.6 Individual adverse event reports [§804.28]

Distributors should use FDA Form 3500A (mandatory MedWatch form) to submit individual adverse event reports, but it is not required at this time. This two page form is intended for required reporting of problems with FDA regulated products. It is divided into eight sections or blocks – seven for reporting medical device problems. Five blocks are used by user facilities/distributors primarily and two blocks are used by device manufacturers.

A copy is included in Appendix C.

Distributors should provide:

- information about the patient;
- type of adverse event;
- a description of the event;
- relevant laboratory/test data;
- manufacturer and identification of the suspect device and certain other information about the device;
- initial reporter of the event;
- user facility/distributor name, address and contact;

- device problem codes for the event and patient; and
- where and when the report was sent.

2.7 Exemptions and alternative reporting [§804.33]

Distributors may submit written requests to FDA for exemptions from any or all of the reporting requirements. Such requests are sent to:

Food and Drug Administration
Center for Devices and
Radiological Health (HFZ-530)
Attn: Leighton Hansel
1350 Piccard Drive
Rockville Maryland 20850

FDA may grant the requested exemption and change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time periods. These requests must include the information necessary to identify the firm and device and an explanation of why the request is justified.

In granting an exemption, FDA may impose other reporting requirements to ensure the protection of the public health and safety. Or, FDA may revoke (in writing) alternative reporting options if it determines that protection of the public health justifies a return to the requirements as stated in this part.

3. PROCEDURE FOR REPORTING ADVERSE EVENTS

This procedure outlines steps a distributor can follow and questions to answer before deciding whether a distributor report should be filed and filing requirements.

3.0 Steps for reporting adverse events: "questions to ask"

3.1 Am I a distributor as defined in the MDR regulation [§804.3(d)]?

As defined by the regulation, only persons who further the marketing of a device from the original place of manufacture to the person who makes final delivery to the ultimate user are defined as distributors and are required to file reports. A person who makes final delivery or sale to the ultimate user does not meet the definition of distributor and is, therefore, not required to report adverse events under MDR. This person is usually a retail level distributor or dealer.

If you are a distributor subject to MDR reporting as defined by the MDR regulation, **go to Step 3.2**

If you are not a distributor as defined by the MDR regulation, **stop** here, since the reporting requirements do not apply to you.

3.2 What kind of distributor am I?

There are two kinds of distributors – distributors other than importers (domestic distributors) and distributors who receive devices from another country (importers).

3.3 From whom and where was the information about the event received?

Information can be received from any source, including user facilities, individuals, or medical or scientific literature (published or unpublished).

3.4 As a domestic distributor, when and to whom do I file reports?

- A report is to be submitted to FDA and the manufacturer if the information reasonably suggests that there is a probability that the device has caused or contributed to a death, serious illness or serious injury; or,
- When the distributor becomes aware of a malfunction and the information reasonably suggests that there is a probability that the device would cause a death, serious illness, or serious injury, if the malfunction were to recur.

Information that "reasonably suggests that there is a probability" is information, including professional, scientific, or medical facts, observations, or opinions, that would cause a reasonable person to believe that a reportable event occurred.

3.5 As an importer, when and to whom do I submit reports?

- A report is to be submitted to FDA and the manufacturer if the information reasonably suggests that the device may have caused or contributed to a death or serious injury; or,
- When the distributor/importer becomes aware of a malfunction and the device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

3.6 Submit a written report or additional information within 10 working days to the following:

**Food and Drug Administration
Center for Devices and
Radiological Health
Distributor Report
P. O. Box 3002
Rockville, MD 20847-3002**

4. QUESTIONS AND ANSWERS

4.1 What is the distributors's role in the MDR process?

The distributor's role is one of an intermediary that forwards data from user facilities, or any other source, to FDA and the manufacturer. Distributors are not required to investigate the cause of adverse device events. They are required to assess whether or not a reportable event has occurred.

4.2 My firm sells directly to hospitals, physicians, and patients. Am I a distributor?

No. Since you dispense devices directly to the ultimate user or consumer, your firm is not considered a distributor subject to regulation and, therefore, you are not subject to the MDR reporting requirements.

4.3 I am a sales agent for several manufacturers. Am I a distributor?

No. Sales representatives are not considered to be distributors, unless they take possession and resell products to someone who makes final delivery or sale to the ultimate user.

4.4 I am registered as a device manufacturer, and I also distribute my own devices. Do I also register as a medical device distributor?

If a part of the parent organization is responsible for the distribution of the product, that site must register with FDA as a medical device distributor. For

purposes of medical device reporting, the manufacturer may submit one report for both entities.

4.5 What if a firm manufactures devices and distributes devices made by other firms?

In this instance, the firm must submit MDR reports to FDA based on the manufacturer reporting requirements of Title 21 Code of Federal Regulation (CFR) Part 803, if a reportable event concerning manufactured products occurs. It must also submit MDR reports to the FDA and the manufacturer as required by the distributor reporting requirements of Part 804, if it receives reportable events for the devices it distributes.

4.6 A distributor (Firm A) sells a device to another firm (Firm B) that rents/leases the device to a user facility. Who files a MDR report?

Firm A would file MDR reports. A distributor (such as Firm A) who furthers marketing between the manufacturer and the person or firm who makes final delivery or sale (such as a retail pharmacy or home care dealer) without changing the label or package is subject to the MDR reporting requirements of Part 804 and must file an MDR report. A distributor (Firm B) that makes final delivery or sale to the ultimate user is not required to submit MDR reports.

A distributor (such as Firm B) that makes final delivery or sale to the ultimate user is not considered a distributor under the

regulation and not subject to the reporting requirements of Part 804.

4.7 Is an importer required to file an MDR report when hearing about an event which occurs outside the U.S.?

This event would require an MDR if the device is also distributed in the United States. A report is required when a distributor becomes aware of information from **any** source that a device marketed by the distributor may have caused or contributed to a death, serious injury, or malfunction that could cause or contribute to a death or serious injury.

4.8 Is there a report form for annual certification reports?

Yes, Form 3381. The regulation does not require the use of a form, but FDA encourages its use and plans to make the form mandatory.

4.9 Are importers still subject to the MDR requirements contained in Part 803?

No, the regulations in Part 804 supersede the requirements of Part 803, solely as they apply to importers.

4.10 If I have questions about complying with the MDR regulation, whom do I call?

Questions regarding the MDR regulation can be answered by the Division of Surveillance Systems, Office of Surveillance and Biometrics, Center for Devices and Radiological Health (CDRH), at (301) 594-2735.

4.11 A domestic distributor imports a device from a foreign manufacturer, then sold the device to other domestic distributors with the foreign manufacturer's name on the label. Who reports the MDR event and to whom?

Each distributor in the distribution chain, except the person who makes final delivery or sale to the ultimate user, must file an MDR report to FDA and/or the manufacturer.

4.12 If a distributor submits an MDR report to FDA and also notifies the manufacturer, is the manufacturer expected to also notify FDA regarding this same event?

Yes, if the event is reportable under the MDR requirements of Part 803 for manufacturers.

4.13 I am a manufacturer who distributes my own and other companies' devices. For those devices that I distribute, how do I handle reports from customers regarding malfunctions?

You may submit reportable malfunctions as a manufacturer and need not file reports as a distributor for devices that you manufacture and distribute. For devices which you distribute but do not manufacture, you must report as a distributor provided you do not distribute the devices directly to the ultimate user.

Appendix A

DISTRIBUTOR ANNUAL CERTIFICATION SCHEDULE

First Letter of Owner Or Operator Name	Date FDA Will Mail Forms	Date Firm Must Submit Reports
A,B,C,D,E	March	April
F,G,H,I,J,K,L,M	June	July
N,O,P,Q,R	August	September
S,T,U,V,W,X,Y,Z	November	December

Appendix B

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION CDRH MEDICAL DEVICE REPORTING P.O. BOX 3002 ROCKVILLE, MD 20847-3002	FORM APPROVED: OMB No. 0910-0059 EXPIRES: 02/28/99
MEDICAL DEVICE REPORTING - ANNUAL CERTIFICATION	
PART 1	
<p>NOTE: This form is authorized by Section 519 of the Food, Drug and Cosmetic Act (21 U.S.C. 360). Failure to report this information is a violation of Section 301(p) of the Act (21 U.S.C. 331(p)). Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2) (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C. 1001.</p>	
<p>INSTRUCTIONS: Please complete Part 1, then complete and sign Part 2 in order to comply with the certification requirement. The certification period and FDA registration number shown on Part 1 must be repeated on each attached Part 2. More than one Part 2 must be completed if the number of entries exceeds the number of rows in Part 2, item 3. Return all parts of this report to the address listed above.</p>	
<p>1. This Certification Covers the Period</p> <div style="text-align: center; margin-top: 10px;"> ____ / ____ / ____ M M D D Y Y Y Y To ____ / ____ / ____ M M D D Y Y Y Y </div>	
2. REPORTING SITE INFORMATION	3. CERTIFICATION INFORMATION
a. FDA Registration Number	a. Name of Person Completing Certification
b. Firm Name	b. Title
c. Street Address	c. Street Address
d. City e. State f. ZIP Code	d. City e. State f. ZIP Code
g. Country/Postal Code (if not U.S.)	g. Telephone Number (Include area code and, if applicable, extension)
h. Type of Firm (Check all that apply) <input type="checkbox"/> Manufacturer <input type="checkbox"/> Distributor <input type="checkbox"/> U.S. Agent of a Foreign Manufacturer	
<p>Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:</p> <p style="margin-left: 40px;">DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0059) Hubert H. Humphrey Building, Room 531-H 200 Independence Avenue, S.W. Washington, DC 20201</p> <p style="margin-left: 40px;">(Please DO NOT RETURN this form to this address.)</p> <p style="margin-left: 40px;"><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i></p>	

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Appendix C

For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Form Approved: OMB No. 0910-0291 Expires: 1/31/96
See OMB statement on reverse

Mfr report #
UF/Dist report #
FDA Use Only

Page ____ of ____

A. Patient information

1. Patient Identifier	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
-----------------------	--	--	---

B. Adverse event or product problem

1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> other: _____	
3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1	
#2	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration from to (or best estimate))
#1	#1
#2	#2
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1	#1
#2	#2
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)	
- -	

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device
	<input type="checkbox"/> health professional
	<input type="checkbox"/> lay user/patient
	<input type="checkbox"/> other: _____
5. Expiration date (mo/day/yr)	6. model #
7. If implanted, give date (mo/day/yr)	catalog #
8. If explanted, give date (mo/day/yr)	serial #
	lot #
	other #
9. Device available for evaluation? (Do not send to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mo/day/yr)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Initial reporter

1. Name & address		phone #
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk



FDA Form 3500A (6/93)

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

PLEASE TYPE OR USE BLACK INK

Medication and Device Experience Report

(continued)

Submission of a report does not constitute
an admission that medical personnel, user
facility, distributor, manufacturer or product
caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

Refer to guidelines for specific instructions

Page ____ of ____

FDA Use Only

F. For use by user facility/distributor-devices only

1. Check one <input type="checkbox"/> user facility <input type="checkbox"/> distributor		2. UF/Dist report number	
3. User facility or distributor name/address			
4. Contact person		5. Phone Number	
6. Date user facility or distributor became aware of event (mo/day/yr)	7. Type of report <input type="checkbox"/> initial <input type="checkbox"/> follow-up # _____	8. Date of this report (mo/day/yr)	
9. Approximate age of device	10. Event problem codes (refer to coding manual) patient code _____ - _____ - _____ device code _____ - _____ - _____		
11. Report sent to FDA? <input type="checkbox"/> yes _____ (mo/day/yr) <input type="checkbox"/> no		12. Location where event occurred <input type="checkbox"/> hospital <input type="checkbox"/> outpatient diagnostic facility <input type="checkbox"/> home <input type="checkbox"/> ambulatory surgical facility <input type="checkbox"/> nursing home <input type="checkbox"/> outpatient treatment facility <input type="checkbox"/> other: _____ specify	
13. Report sent to manufacturer? <input type="checkbox"/> yes _____ (mo/day/yr) <input type="checkbox"/> no			
14. Manufacturer name/address			

G. All manufacturers

1. Contact office - name/address (& mailing site for devices)		2. Phone number	
4. Date received by manufacturer (mo/day/yr)		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other: _____	
6. If IND, protocol #	5. (A) NDA # _____ IND # _____ PLA # _____ pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes		
7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____	8. Adverse event term(s)		
9. Mfr. report number			

H. Device manufacturers only

1. Type of reportable event <input type="checkbox"/> death <input type="checkbox"/> serious injury <input type="checkbox"/> malfunction (see guidelines) <input type="checkbox"/> other: _____		2. If follow-up, what type? <input type="checkbox"/> correction <input type="checkbox"/> additional information <input type="checkbox"/> response to FDA request <input type="checkbox"/> device evaluation	
3. Device evaluated by mfr? <input type="checkbox"/> not returned to mfr. <input type="checkbox"/> yes <input type="checkbox"/> evaluation summary attached <input type="checkbox"/> no (attach page to explain why not) or provide code: _____		4. Device manufacture date (mo/yr)	
		5. Labeled for single use? <input type="checkbox"/> yes <input type="checkbox"/> no	
6. Evaluation codes (refer to coding manual) method _____ - _____ - _____ - _____ results _____ - _____ - _____ - _____ conclusions _____ - _____ - _____ - _____			
7. If remedial action initiated, check type <input type="checkbox"/> recall <input type="checkbox"/> notification <input type="checkbox"/> repair <input type="checkbox"/> inspection <input type="checkbox"/> replace <input type="checkbox"/> patient monitoring <input type="checkbox"/> relabeling <input type="checkbox"/> modification/adjustment <input type="checkbox"/> other: _____		8. Usage of device <input type="checkbox"/> Initial use of device <input type="checkbox"/> reuse <input type="checkbox"/> unknown	
9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number: _____			
10. <input type="checkbox"/> Additional manufacturer narrative and/or 11. <input type="checkbox"/> Corrected data			

The public reporting burden for this collection of information has been estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHIS
Hubert H. Humphrey Building, Room 721-B
200 Independence Avenue, S.W.
Washington, DC 20201
ATTN: PRA

and to:
Office of Management and Budget
Paperwork Reduction Project (0910-0281)
Washington, DC 20503

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FDA Form 3500A - back

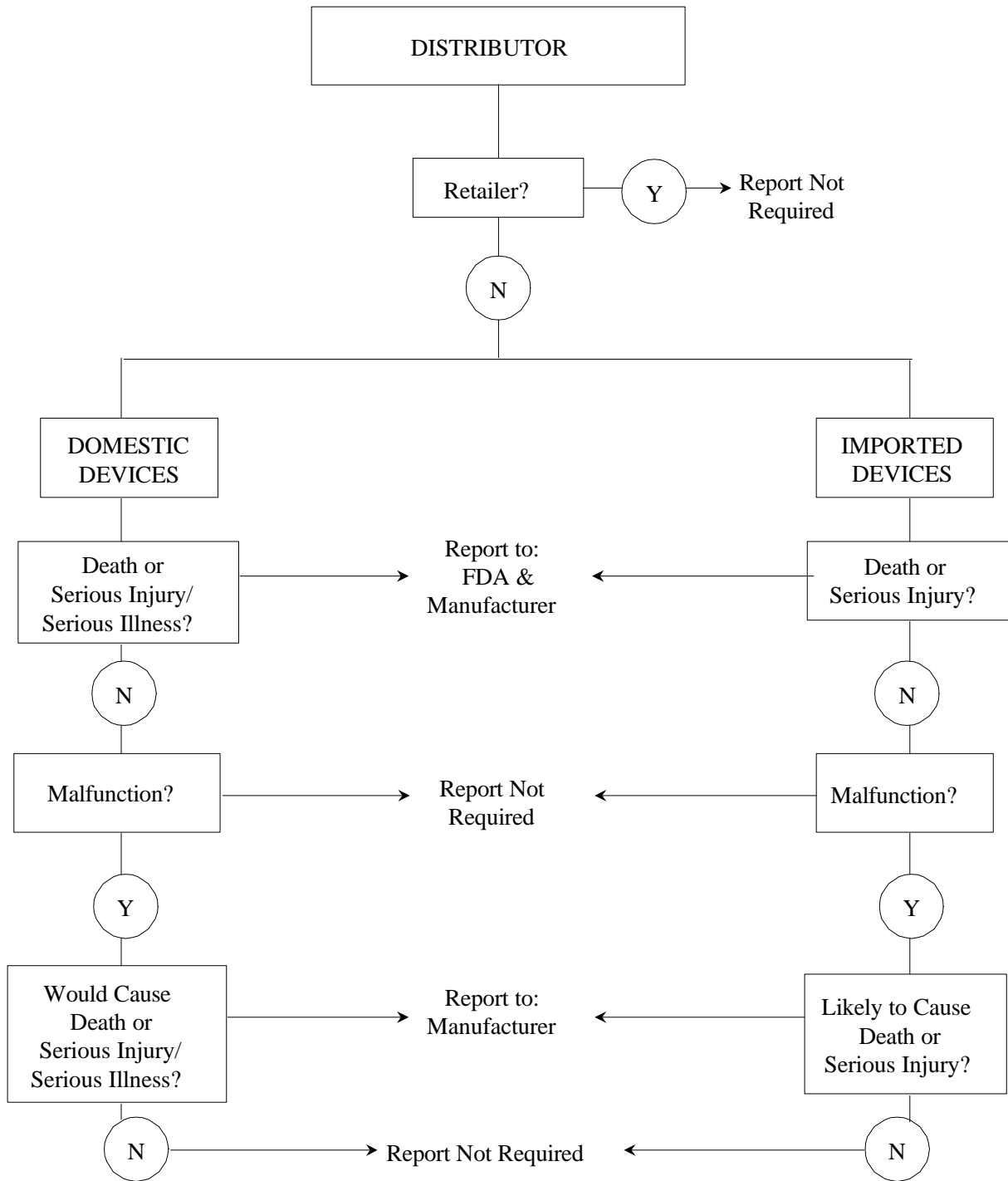


FIGURE 1. Distributor Report Flow Chart